

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE

## STATEMENT BY APPLICANT

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## COMPLETE IF KNOWN

Application Number 09/469,485

Filing Date December 22, 1999

First Named Inventor Q. Zhao et al.

Group Art Unit 1648

Examiner Name Foley

Attorney Docket Number 20369Y

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## OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
BL	✓	Mimms, et al. "Second Generation assays for the detection of antibody to HbsAg using recominant DNA-derived HbsAg". J. VIRAL METHODS 25: 1989, Pg. 211-232.
	✓	Tung, et al. "Characterization of Recombinant Hepatitis B Surface Antigen Using Surface Plasmon Resonance". J. PHARMACEUTICAL SCIENCES 87: 1998, Pg. 76-80.
	✓	Lohman, et al. "Molecular Characterization and Structural Modeling of Immunoglobulin Variable Regions from Murine Monoclonal Antibodies Specific for Hepatitis B Virus Surface Antigen". MOLECULAR IMMUNOL 30: 1993, Pg. 1295-1306.
	✓	Donnelly, JJ., et al. "Adjuvant effects of DNA Vaccines". In VACCINES 97, (Ed. Brown et al., )1997, Pg. 105-111.
	✓	Guerrero, et al. "Model for the Protein Arrangement in HBsAg Particles Based on Physical and Chemical Studies" In VIRAL HEPATITIS AND LIVER DISEASE (Ed. AJ Zuckerman), Pg. 606-613.
	✓	Hauser, et al., "Inudction of Neutralising Antibodies in Chimpanzees and in Humans by a Recombinant Yeast-Derived Heptaitis B Surface Antigen Particle" In VIRAL HEPATITIS AND LIVER DISEASE (Ed. AJ Zuckerman), Pg. 1031-1037.
✓	✓	Ubuka, T. "Protein Disulfide Isomerase-Catalyzed Renaturation of Ribonuclease A Modified By S-Thiolation With Glutathione and Cysteine". BIOCHEM MOL BIOL INT. 38(6): 1996, Pg. 1103-10.
		<del>Valenzuela, et al. "Nucleotide sequence of the gene coding for the major protein of hepatitis B virus antigen". NATURE 280: 1979, Pg. 815-819.</del> <b>DUPLICATE</b>
BL	✓	Valenzuela, P., et al. "Synthesis and assembly of hepatitis B virus surface antigen particles in yeast". NATURE 298: 1982, Pg. 347-350.
	✓	Miyanochara, A., et al. "Expression of hepatitis B surface antigen gene in yeast". PNAS USA 80(1): 1985, Pg. 1-5.
	✓	Wampler, et al. "Multiple chemical forms of hepatitis B surface antigen". PROC. NAT. ACAD. SCI. 82: 1985, Pg. 6830-6834.
	✓	Mishiro, S., et al. "A 49,000-Dalton Polypeptide bearing all antigenic determinants and full immunogenicity of 22-nm Hepatitis B surface antigen particles". J. IMMUNOLOGY 124: 1980, Pg. 1589 - 1593.
	✓	Chen, et al. "Discontinuous epitopes of hepatitis B surface antigen derived from a filamentous phage peptide library". PNAS 93: 1996, Pg. 1997-2001.
	✓	Musiol, et al. "Redox-active bis-cysteiny peptides. I. Synthesis of cyclic cysteinyl peptides by conventional methods in solution and on solid supports". BIOPOLYMERS 34: 1994, Pg. 1553-1562.
✓	✓	Moroder, et al. "Oxidative folding of cysteine-rich peptides vs. Regioselective cysteine pairing strategies". BIOPOLYMERS 40: 1996, Pg. 207-234.

Examiner Signature

Date Considered

6/26/06

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Draw line through citation if not in conformance and not considered.  
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Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.
BE	✓	Qiu, et al. "Identification and Characterization of a C(K/R) TC Motif as a Common Epitope Present in All Subtypes of Hepatitis B Surface Antigen". J. IMMUNOL 156: 1996, Pg. 3350-3356.
	✓	Fahey, R.C., "Biologically Important Thiol-Disulfide Reactions and The Role of Cyst(E)ine in Proteins: An Evolutionary Perspective" University of California, 1977, pgs. 1-30.
	✓	Lyles, M.M., et al., "Catalysis of the Oxidative Folding of Ribonuclease A by Protein Disulfide Isomerase: Dependence of the Rate on the Composition of the Redox Buffer" BIOCHEMISTRY 30, 1991, Pg. 613-619.
	✓	Tleugabulova, D. "Sodium Dodecylsulfate Polyacrylamide Gel Electrophoresis of Recombinant Hepatitis B Surface Antigen Particles" JOURNAL OF CHROMATOGRAPHY B 707 1998, PG. 267-273.
	✓	Kennedy, R.C. "Idiotypic Networks in Hepatitis B Virus Infections" CURR TOPICS MICROBIOL. IMMUNOL. 119, 1985, PG. 1-13.
	✓	Kennedy, R. C. et al., "Characterization of Anti-Hepatitis B Surface Antigen Monoclonal Antibodies" INTERVIROLOGY 19, 1982, PG. 176-180.
	✓	Antoni, B. A. et al., "Disulfide Bond Analysis in Hepatitis B Surface Antigen by Mutagenesis of Cyseine esidues Within The Major Antigenic Determinant Region" FASEB J 2 (5) 1988 Abstract 6020.
	✓	DéFlora, S. et al., "Enhanced Metabolic Activation of Chemical Hepatocarcinogens in Woodchucks Infected with Hepatitis B Virus" CARGINOGENESIS 1989 10(6), PG. 1099-106.
	✓	Bruce, S. A. et al., "Mutations of Some Critical Amino Acid Residues in the Hepatitis B Virus Surface Antigen" JOURNAL OF MEDICAL VIROLOGY 46:157 1995 PG 157-161.
	✓	Ashton-Rickardt, P. G. et al., "Mutants of the Hepatitis B Virus Surface Antigen That Define Some Antigenically Essential Residues in the Immunodominant a Region" JOURNAL OF MEDICAL VIROLOGY 29 1989, PG 196-203.
	✓	Dreesman, G. R., et al., "Synthetic Hepatitis B Surface Antigen Peptide Vaccine" ADV EXP MED BIOL. 185, 1985, PG. 129-137.
	✓	Luengrojanakul, P. et al., "Common and Subtypic Determinants of Hepatitis B Surface Antigen Particles: Susceptibility to Reduction and/or Alkylation Evaluated with Monoclonal Antibodies" JPN J EXP MED 60 (5), 1990, PG. 253-261.
	✓	Antoni, B. A. et al., "Site-Directed Mutagenesis of Cysteine Residues of Hepatitis B Surface Antigen Analysis of Two Single Mutants and the Double Mutant" EUR J BIOCHEM 222(1) 1994 pg. 121-127
	✓	Zheng, Y. W., et al., "Negative Regulation of Hepatitis B Virus Gene Expression and Replication by Oxidative Stress" J BIOL CHEM 269(12) 1994 Pg. 8857-8862.
	✓	Antoni, B. A. et al. "Site Directed Mutagenesis of the Hepatitis B Surface Antigen Gene Creation of a Free-Sulphydryl Group and Modification of the Protein in the 22NM Particle Structure" J MED VIROL 21(4) 1987 ABSTRACT 150

Examiner Signature

B. A. Antoni

Date Considered

6/26/96

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BK	✓	Mangold, C. M. et al., "Secretion and Antigenicity of Hepatitis B Virus Small Envelope Proteins Lacking Cysteines in the Major Antigenic Region" VIROLOGY 211(2) PG. 535-543.
	✓	Fernandes, C. L. et al., "Elevations of Hepatic Quinone Reductase, ...Isoforms in Mice With Chronic Hepatitis: A Compensatory Response to Injury" ARCH BIOCHEM BIOPHYS 331(1) 1996 PG. 104-116.
	✓	Diminsky, D. et al., "Comparison Between Hepatitis B Surface Antigen...Composition, Structure and Immunogenicity" VACCINE 15(6-7) 1997, PG. 637-647.
	✓	Altomare, E. et al., "Hepatic Glutathione Content in Patients With Alcoholic and Non Alcoholic Liver Diseases" LIFE SCI 43(12) 1988, PG. 991-998.
	✓	Ionescu-Matiu, I. et al., "Epitopes Associated With A Synthetic Hepatitis B Surface Antigen Peptide" J. IMMUNOL. 130 1983 PG. 1947-1952.
	✓	Yamamoto, K. et al., "Naturally Occurring Escape Mutants of Hepatitis B Virus with Various Mutations in the S Gene in Carriers Seropositive for Antibody to Hepatitis B Surface Antigen" J VIROL. 68(4) 1994 PG. 2671-6.
	✓	Ohnuma, H. et al., "Synthetic Oligopeptides Bearing A Common or Subtypic Determinant of Hepatitis B Surface Antigen" J. IMMUNOL. 145(7) 1990, PG. 2265-2271.
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	✓	Huovila, A. J. et al., "Hepatitis B Surface Antigen Assembles in a Post-ER, Pre-Golgi Compartment" J. CELL BIOL. 118, (6) 1992, PG. 1305-1320.
	✓	Kennedy, R. C. et al., "Common Idiotypic Determinant Associated with Human Antibodies to Hepatitis B Surface Antigen" J. IMMUNOL. 130 1983 PG. 385-389.
	✓	Zajac, B.A. et al., "Improvements in the Immunogenicity and Purity of a Genetically Engineered Hepatitis B Vaccine" HEPATOLOGY, VOL 8, NO. 5, 1988, Abstract 416
	✓	Manivel, V. et al. "A Synthetic Peptide Spontaneously Self-Assembles to Reconstruct A Group-Specific, Conformational Determinant of Hepatitis B Surface Antigen" J OF IMMUNOL. 148 (12) 1992, PG. 4006-4011.

Examiner Signature

Bryan Campbell

Date Considered

6/26/06

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